

Impact of Huge-Seller Repricing on Price Trend for Reimbursable Cancer Drugs in Japan

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Objectives

Japan uses international reference pricing (IRP) to ensure its drug prices are not substantially higher or lower than prices in its reference countries. However, Japan also employs different strategies to reprice medicines over time. One of these – the high-seller repricing rule – specifically targets drugs with large market sales. This analysis aims to identify and examine the price trends in Japan of top-seller cancer drugs compared to those in France, Germany, and the United Kingdom (UK).

Methods

The overall 5-year price trend for all reimbursed branded cancer drugs in Japan, France, Germany, and the UK, with an available pricing history in GlobalData's POLI database, was examined. A separate analysis was conducted into the price trend for the top four highest-selling cancer therapies in FY2023 in Japan compared to the same product, dosage and pack size in France, Germany, and the UK over the period from first price listing to 31 May 2024. The four top selling cancer drugs examined are Merck & Co.'s (US) Keytruda (pembrolizumab), Ono Pharmaceutical's (Japan) Opdivo (nivolumab), and AstraZeneca's (UK) Imfinzi (durvalumab) and Tagrisso (osimertinib).

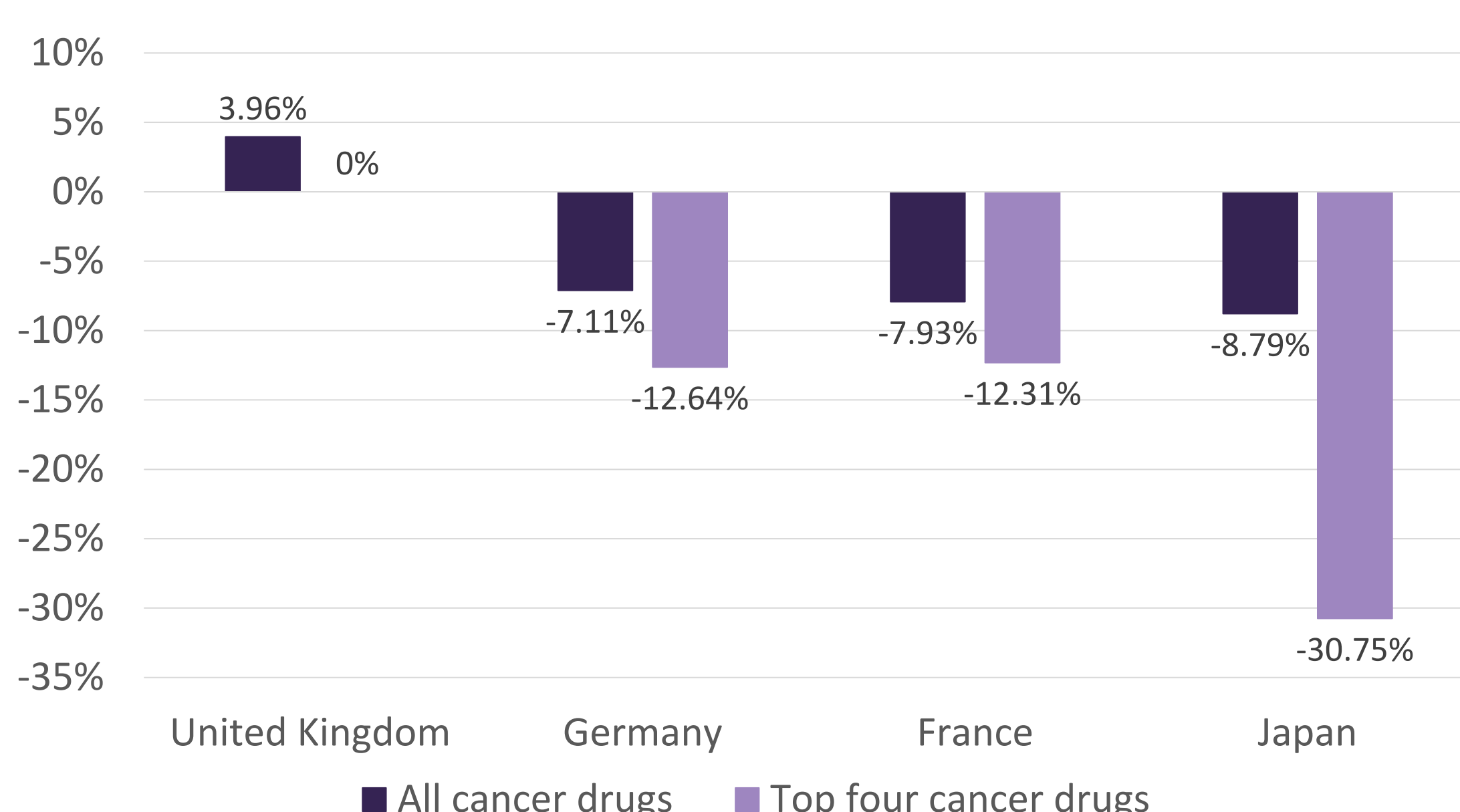
Results

To ensure its drug prices are competitive compared with overseas markets at launch, the Japanese Ministry of Health, Labour, and Welfare MHLW (MHLW) utilizes IRP and caps the price in Japan at the comparable level of prices in four reference markets: the US, the UK, Germany and France. Additionally, to contain pharmaceutical spending, the MHLW introduced a series of repricing regulations in the past decade. As repricing measures take effect, there are concerns that over time the prices of patent-protected drugs in Japan are no longer aligned with those in the European countries in Japan's IRP basket.

Between 1 January 2019 and 31 December 2023, according to POLI data, the NHI drug prices dropped by 10.97% for patent-protected products in Japan. Over the same period, prices of patent-protected products dropped by 6.72% in Germany and 4.12% in France. The prices of patent-protected products increased in the UK. This initial review of price trends demonstrates a clear risk that a branded drug could receive larger price cuts in Japan than in the other three European markets.

Among Japan's repricing strategies, the huge-seller repricing rule targets top selling products and leads to significantly price reductions on popular treatments. Analysis of pricing data from GlobalData's POLI database for top-selling drugs Keytruda, Opdivo, Imfinzi and Tagrisso compared to all reimbursed cancer drugs indicates that Japan's price reduction rates for the top-selling cancer drugs was significantly higher than its average 5-year price reduction rate for all reimbursed cancer drugs.

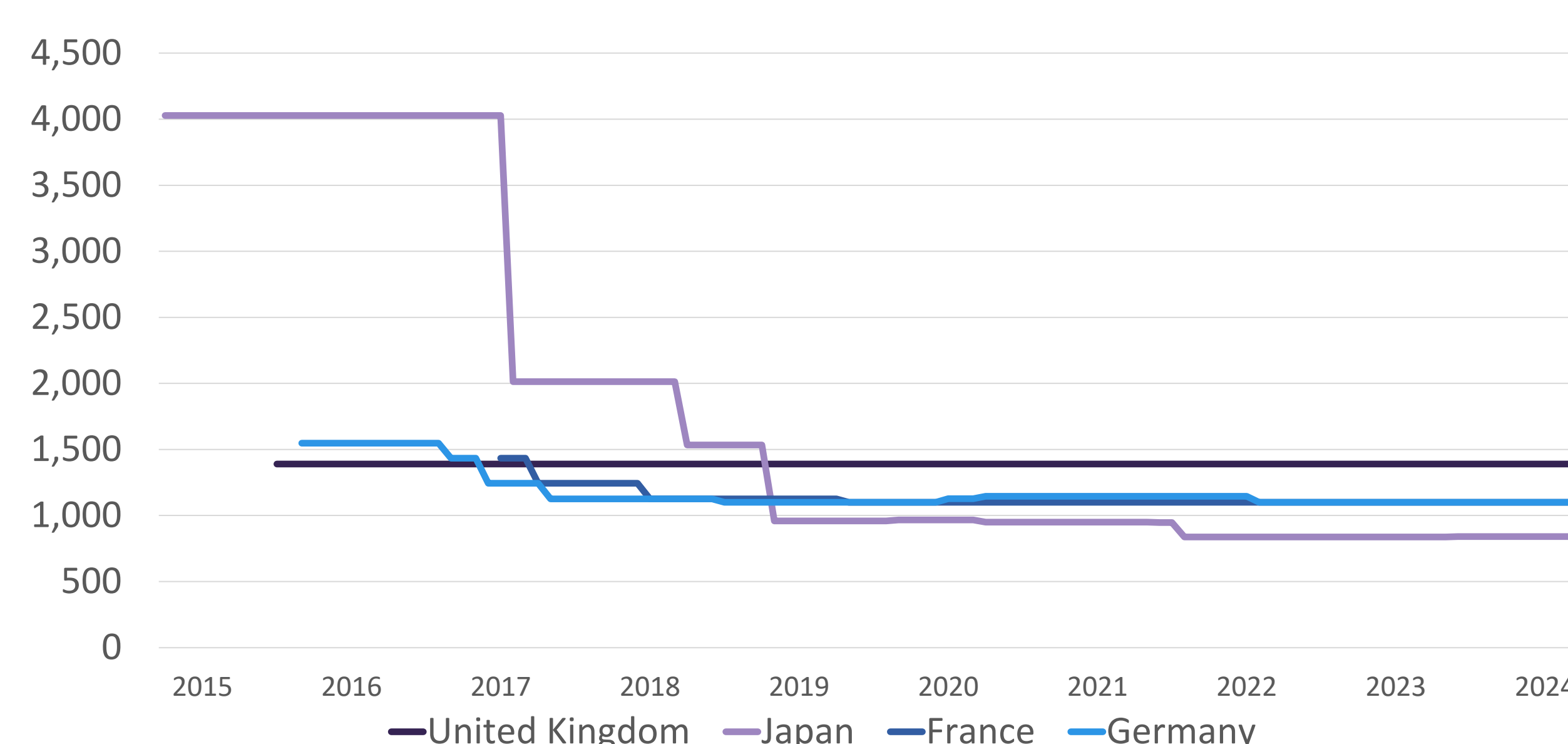
Pharmaceutical Price Trends of reimbursed cancer drugs, 1 November 2019 – 31 October 2024



The 5-year price decline for these four drugs is more than twice as high in Japan than in Germany and France. The average price reduction rate for all reimbursed cancer drugs is highest in Japan but is more in line with Germany and France.

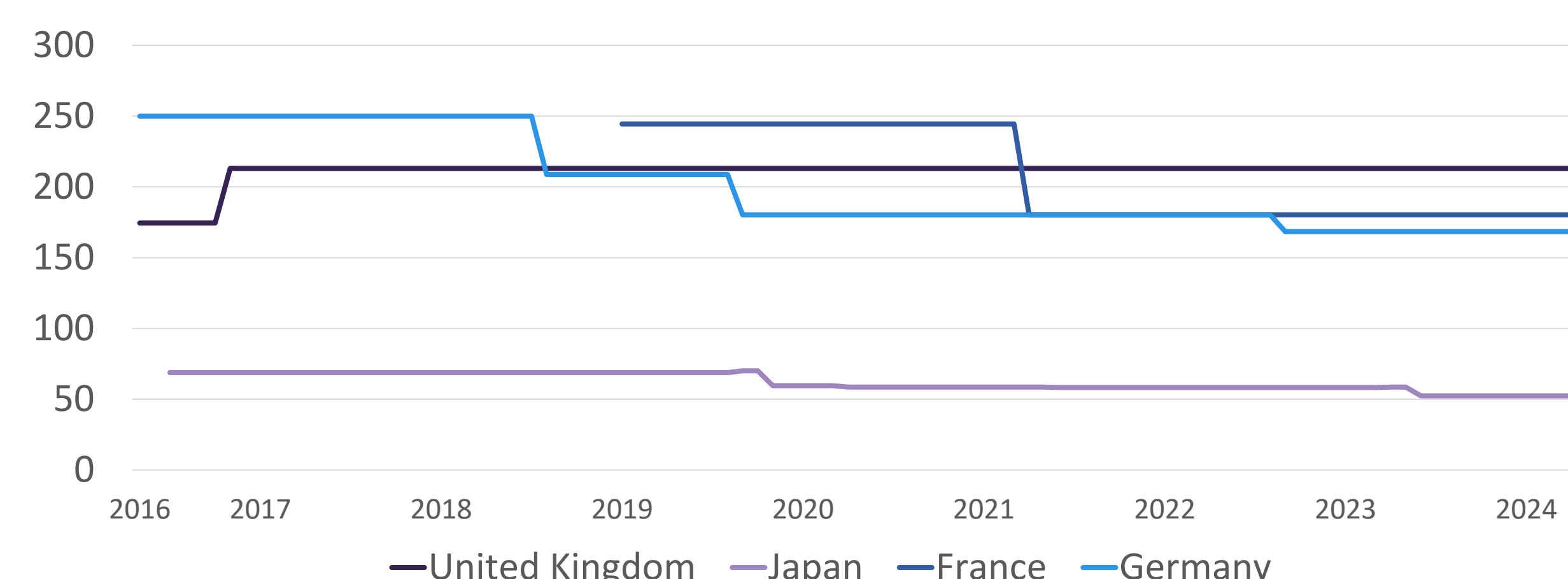
The huge-seller repricing scheme is the main factor causing the Japanese price of the popular cancer drug, Opdivo, to drop to the lowest level among the four markets, despite starting out at the highest initial level. Opdivo was first launched in Japan at the end of 2014. Thanks to its early launch in Japan, Opdivo obtained a high initial listed price. However, the price incentive was soon eroded when a 50% price reduction was applied on Opdivo under the huge-seller rule in 2017. The drug then received four subsequent price cuts, each one triggered by the huge-seller rule, between 2018-24. As of 2024, the Japanese price of Opdivo was the lowest among the four markets, set at around 50%-65% of the prices in the three European reference markets.

Price History of Opdivo in four markets, since first price date (USD)



Among the four top selling cancer drugs, Tagrisso had the smallest price reduction rate from initial listing: 23.86%, compared to 82.25% for Opdivo, 47.97% for Keytruda, and 33.55% for Imfinzi. However, the initial listed price of Tagrisso in Japan was already at a lower level than the initial prices in the three European reference markets.

Price History of Tagrisso in four markets, since first price date (USD)



Conclusions

Japan's re-pricing rules have already resulted in substantially higher price reductions on huge-seller cancer drugs and slightly larger price cuts for all reimbursed cancer drugs in the past five years compared to its European reference countries. While top selling drugs are mostly spared from the periodic price revision scheme, which is based on market prices, due to their innovativeness values, the huge-seller repricing scheme has led to steeper cuts in prices in Japan compared to those observed in Japan's three European reference countries. Between 2019 and 2024, the price reduction rate of the top four selling cancer drugs in Japan was more than double the reduction rates in Germany and France. The huge seller re-pricing rule, which allows a statutory price cut rate of up to 50%, plays an increasingly important role in driving price declines in Japan, especially for drugs with high innovativeness and high Japanese sales. For the four top selling drugs examined in greater details in this study, prices in Japan are now the lowest among the four markets. This trend may discourage early launches and investment in the Japanese market, since the long-term profitability of innovative drugs during their patent-protection period is not guaranteed.